SAT Report for Case # P-17-0382

General

[redacted]

Report Status: In Progress **Status Date:** 08/30/2017

CRSS Date: 08/31/2017 **SAT Date:** 09/01/2017 **SAT Chair:** K.Moran

Consolidated PMN?

Consolidated Set:

Submitter: Chemtura Corporation

CAS Number: 1454803-04-3

Ecotox Related Cases: [redacted]

Health Related Cases: [redacted]

Chemical Name: Amides, tallow, N,N-bis(2-hydroxypropyl)

Use: Friction modifier for motor oils lubricants, mainly used in passenger vehicles. [redacted]

Trade name: MLA-3202, Naugalube® OFM 3202

PV Max (kg/yr): [redacted]

Ecotox Assessor: T. Wright **Fate Assessor:** Frank Antwi **Health Assessor:** A.Babcock

Physical Chemical Information

Molecular Weight:	397.65	**Physical State - Neat:**	Liquid		
Percent 500:		**Percent 1000:**			
Melting Point (Measured):	-50.00 - 10.00	**Melting Point (est):**		**MPD (EPI):**	
Vapor Pressure:		**Vapor Pressure (est):**	< 0.000001	**VP (EPI):**	
Water Solubility:	0.000540	**Water Solubility (EST):**		**Water Solubility (EPI):**	
Log Kow:				**Log Kow (EPI):**	
Log P:		**Log P Comment:**			

SAT Concern

Ecotox Rating (1):	3	**Ecotox Rating Comment (1):**	PMN substance
Ecotox Rating (2):		**Ecotox Rating Comment (2):**	
Health Rating (1):	2	**Health Rating Comment (1):**	
Health Rating (2):		**Health Rating Comment (2):**	

PBT Ratings

Persistence	Bioaccumulation	Toxicity	Comments
3	1	2	

Exposure Based Review (Health)?	Y
Exposure Based Review (Ecotox)?	Y
SAT Keywords:	SENS, DEVEL, SPLEEN, LIVER, THYROID, AQUATOX.

Fate Assessment Summary: P-17-0382

FATE: Estimations for typical with
C18:1 acyl chain, C24H47NO3, MW 397.65
Liquid with MP = -50 - 10 °C
(M)
log Kow = 6.45 (E)
S = 0.540 mg/L at 25 °C (M)
VP <
1.0E-6 torr at 25 °C (E)
BP > 400 °C (E)
H < 1.00E-8 (E)

log Koc = 3.53 (E)
log Fish BCF = 2.6 (360) (E)
log Fish BAF =
2.12 (130) (E)
POTW removal (%) = 90-99 via sorption and biodeg; OECD
302C(Mod MITI): 77.9%/28d;
OECD 301B (Mod Sturm CO2 ev): 46-50%/28d
(10-day window not met) NRB; OECD 111(Hydrolysis): t1/2(pH4,7,9):
9249d/-1687d/-47d @ 20C, 20d/18d/18d @ 50C, 18d/33d/45d @ 60C.
Time
for complete ultimate aerobic biodeg = wk
Sorption to soils/sediments
= strong
PBT Potential: P3B1
*CEB FATE: Migration to ground water
= slow
Bioconcentration factor to be put into E-FAST: 130

PMN
Material:
Overall wastewater treatment removal is 90-99% via sorption
and biodegradation.
Sorption to sludge is strong based on measured
data for the PMN (OECD 117 (Log Kow): 5.3 - > 7.2 and OECD 121 (Log
Koc): 5.4 - > 6.3).

	Air Stripping (Volatilization to air) is negligible based on the estimated Henry's Law Constant. Removal by biodegradation in wastewater treatment is high based on measured data for the PMN (OECD 301B (Mod Sturm CO2 Ev): 46-50%/28d, 10-day window not met; OECD 302C (Modified MITI): 77.9%/28d). Destruction of the substance in wastewater treatment is complete based on measured data for the PMN (OECD 301B (Mod Sturm CO2 Ev): 46-50%/28d, 10-day window not met; OECD 302C (Modified MITI): 77.9%/28d). The aerobic aquatic biodegradation half-life is weeks based on measured data for the PMN (OECD 301B (Mod Sturm CO2 Ev): 46-50%/28d, 10-day window not met; OECD 302C (Modified MITI): 77.9%/28d). The anaerobic aquatic biodegradation half-life is greater than months based on the aerobic biodegradation half-life. The anaerobic biodegradation half-life is projected to be greater or equal to the aerobic biodegradation half-life. Sorption to soil and sediment is strong based on measured data for the PMN (OECD 117 (Log Kow): 5.3 - > 7.2 and OECD 121 (Log Koc): 5.4 - > 6.3). Migration to groundwater is slow based on measured data for the PMN (OECD 117 (Log Kow): 5.3 - > 7.2 and OECD 121 (Log Koc): 5.4 - > 6.3). PMN Material: High Persistence (P3) is based on the anaerobic biodegradation half-life. Low Bioaccumulation potential (B1) is based on BCFBAF model estimates. Bioconcentration/Bioaccumulation factor to be put into E-Fast: 130
Removal in WWT/POTW (Overall):	90-99

Condition	Rating Values w/ Rating Description	Comment
WWT/POTW Sorption:	3	

Condition	Rating Values w/ Rating Description	Comment
WWT/POTW Stripping:	4	
Biodegradation Removal:	2	
Biodegradation Destruction:	2	
Aerobic Biodeg Ult:	2	
Aerobic Biodeg Prim:		
Anaerobic Biodeg Ult:	4	
Anaerobic Biodeg Prim:		
Hydrolysis (t1/2 at pH 7,25C) A:		
Hydrolysis (t1/2 at pH 7,25C) B:		
Sorption to Soils/Sediments:	2	
Migration to Ground Water:	2	
Photolysis A, Direct:		
Photolysis B, Indirect:		
Atmospheric Ox A, OH:		
Atmospheric Ox B, O3:		

Health Assessment

Health Summary: Absorption is poor- moderate through skin, poor through lung, and moderate through the GI tract (pchem). Uncertain concern for sensitization based on conflicting study results provided by the submitter and positive skin sensitization data for the analog coconut fatty acid amide of diethanolamine [redacted]; further assessment is needed. Uncertain concern for spleen and liver toxicity based on a submitted repeated dose study; further assessment is needed. Uncertain concern for developmental toxicity based on a submitted developmental and

reproduction toxicity test and uncertain developmental neuro concerns based on data for analogs coconut oil acid diethanolamine condensate (CAS RN 68603-42-9) with reported thyroid gland hyperplasia following dermal exposure to mice.There is a marginal concern for oncogenicity based on CAS
RN 68603-42-9 and CAS RN 120-40-1 (lauric acid diethanolamine condensate),
where one analog was reported to be positive after dermal administration and the other analog was equivocal. There is concern for irritation to all tissues, and lung effects if inhaled based on the surfactant properties of the PMN material.

Routes of Exposure: Dermal Drinking Water
Inhalation

Test Data Submitted

Test Data Submitted: Test
data submitted with PMN:
(-) Salmonella and E.coli gene mutation assay
with and without activation;
(-) chromosomal aberrations assay in
peripheral human lymphocytes with and without activation;
(-) gene
mutation assay in L5178Y mouse lymphoma cells with and without activation;

(-) in vitro skin corrosion assay in reconstructed human epidermis;

(-) in vitro skin irritation in reconstructed human epidermis;
(-)
skin irritation, rabbits;
(-) eye irritation based on an in vitro
bovine corneal opacity and permeability test;
(-) eye irritation,
rabbits;
(+) skin sensitization, local lymph node assay;
(-) skin
sensitization, Buehler skin sensitization assay;
acute oral LD50 >
5000 mg/kg-bw, rat;
acute dermal LD50 > 5000 mg/kg-bw, rat;

28-day oral repeated dose study with a NOEL of 300 mg/kg bw and a NOAEL of 1000 mg/kg-bw based on reduced spleen weights with the absence of
hematopoiesis and hepatocellular hypertrophy (submitter claimed non-adverse, further review needed);

	reproduction/developmental toxicity test with a NOAEL of 1000 mg/kg-bw (highest dose tested) as stated by the submitter, but noted maternal toxicity was reported at 300 mg/kg bw and greater and a complete litter loss was reported at 1000 mg/kg bw (further review needed);

Ecotox Assessment

Test organism	Test Type	Test Endpoint	Predicted	Measured	Comments
Fish	96-h	LC50	*	0.5	Est. for oleic amide (33% of PMN); M: awaiting study validity
Daphnid	48-h	LC50	*	0.14	Est. for oleic amide (33% of PMN); M: awaiting study validity
Green Algae	96-h	EC50	0.02	0.43	" "
Fish	-	Chronic Value	0.003	0.05	Est. for oleic amide (33% of PMN); M: awaiting study validity; ACR10 (M)
Daphnid	-	Chronic Value	0.02	0.014	Est. for oleic amide (33% of PMN); M: awaiting study validity; ACR10 (M)
Green Algae	-	Chronic Value	0.1	0.36	Est. for oleic amide (33% of PMN); M: awaiting study validity

Factors	Most Sensitive Endpoint	Assessment Factor	CoC	Comment
Acute Acquatic:		4	5	Acute/Chronic; Based on predicted algal EC50
Chronic Acquatic:		10	1	Acute/Chronic; Based on predicted fish ChV

Ecotox Route of Exposure?	All releases to water

Factors	Values	Comments
SARs:	Amides	
SAR Class:	Amides	

Factors	Values	Comments
TSCA NCC Category?	None	

Recommended Testing

Ecotox Value Comments

Predictions are based on QSARs for amides (ECOSAR V2.2); MW 398; Log Kow = 6.45 (P); liquid with a MP = -50-10C (M); S = 0.54 mg/L (M); effective concentrations based on 100% active ingredients and mean measured concentrations; hardness <150 mg/L as CaCO3; and TOC <2.0 mg/L.

Ecotox Factors Comments

Environmental Hazard: Environmental hazard is relevant to whether a new chemical substance is likely to present unreasonable risks because the significance of the risk is dependent upon both the hazard (or toxicity) of the chemical substance and the extent of exposure to the substance. EPA estimated environmental hazard of this new chemical substance using the Ecological Structure Activity Relationships (ECOSAR) Predictive Model (https://www.epa.gov/tsca-screening-tools/ecological-structure-activity-relationships-ecosar-predictive-model).
Based on these estimated hazard values, EPA concludes that this chemical substance has high environmental hazard.

· Substance does not fall within a TSCA New Chemicals Category.
· SAR chemical class of amides.
·
High hazard based on acute and chronic COCs of 5 and 1 ppb, respectively.

Environmental Risk:
· Acute and chronic risks were identified for ecotoxicity.

Testing Recommendations: went to Standard Review